K110772

5. 510(k) Summary

APR 2 8 2011

Andrew Adams
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Submitted: March 17, 2011

Device Name

Trade Name:	BiomarC Fiducial Marker
Classification Name:	Accelerator, Linear, Medical, 21 CFR 892.5050
Common/Usual Name:	Tissue Marker

Predicate Devices

Fiducial Markers (K071614)
BiomarC Tissue Marker (K063193)

Indication for Use

The BiomarC Fiducial Markers are intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization.

Device Description

BiomarC Fiducial Marker is a sterile, pyrogen free, single patient use, pyrolytic carbon coated zirconium oxide discrete marker that is visible on standard radiographs (x-ray, mammography, fluoroscopy, kV, and CT) as well as ultrasound and Magnetic Resonance Imaging (MRI) at up to 4.0 Tesla field strength.

BiomarC Fiducial Marker is supplied pre-loaded in a sterile, pyrogen free, single patient use deployment device. The deployment device consists of a cannula with handle, a push rod with plunger, and bone wax as a marker retaining mechanism.

Technological Characteristics and Performance

BiomarC Fiducial Marker is identical to BiomarC Tissue Marker (K063193) except the indications for use have been expanded in accordance with Fiducial Markers (K071614). Biocompatibility and performance testing confirms that the BiomarC Fiducial Marker is substantially equivalent to the Fiducial Markers for the expanded indications for use (Table 5).

Characteristic	Proposed Device	Predicate Device	Predicate Device
Trade name	BiomarC Fiducial Marker	Fiducial Markers	BiomarC Tissue Marker
510(k) number	K110772	K071614	K063193
510(k) holder	Carbon Medical Technologies, Inc.	Civco Medical Solutions	Carbon Medical Technologies, Inc
Indications for use	The BiomarC Fiducial Markers are intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization.	The Fiducial Markers are intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization. Specifically, they can be used in intracranial diseases as gliomas, neuromas, meningiomas, astroctyomas, arteriovenous malformations, and metastatic carinomas. Additionally, they can be used in the body for treating hepatic, pancreatic, retroperitoneal, paraspinal, skeletal, prostatic and breast tumors.	The BiomarC Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure of for future surgical procedures.
Use	Single use	Single use	Single use
Sterility	Sterilized by EO with an SAL of $1x10^{-6}$	Sterilized by EO with an SAL of $1x10^{-6}$	Sterilized by EO with an SAL of $1x10^{-6}$
Pyrogens	Pyrogen free	Unknown	Pyrogen free
Marker material	Pyrolytic carbon coated zirconium oxide	Gold	Pyrolytic carbon coated zirconium oxide
Device body contact category	Implant device, tissue/bone, permanent	Implant device, tissue/bone, permanent	Implant device, tissue, permanent

(Table 5) (continued)

Safety	Biocompatibility testing for: cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, genotoxicity, implantation (muscle and bone), and haemocompatibility has demonstrated that the BiomarC Fiducial Marker is: non-toxic (cyto and systemic), non-sensitizing, non-irritating (intracutaneous and implantation), non-mutagenic, and non-hemolytic per testing in accordance with the ISO 10993 series.	Biocompatibility testing for: cytotoxicity, sensitization, irritation, systemic toxicity, implantation, and hemolysis has demonstrated that the Fiducial Marker is: non-cytotoxic, non-sensitizing, non-irritating, non-reacting implanted, and non-hemolytic per testing in accordance with ISO 10993.	Biocompatibility testing for: cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, genotoxicity, implantation (muscle), and haemocompatibility has demonstrated that the BiomarC Tissue Marker is: non-toxic (cyto and systemic), non-sensitizing, non-irritating (intracutaneous and implantation), non-mutagenic, and non-hemolytic per testing in accordance with the ISO 10993 series.
Visualization	Visible on standard radiographs (x-ray, mammography, fluoroscopy, kV, and CT), ultrasound, and magnetic resonance imaging (MRI).	Visible on EPID, film, kV and CR.	Visible on standard radiographs (x-ray, mammography, fluoroscopy, kV, and CT), ultrasound, and magnetic resonance imaging (MRI).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Andrew J. Adams
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SAINT PAUL MN 55110-5867

APR 2 8 2011

Re: K110772
Trade/Device Name: BiomarC Fiducial Marker
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 17, 2011
Received: March 21, 2011

Dear Mr. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K110772

Device Name: BiomarC Fiducial Marker

Indications for Use:

The BiomarC Fiducial Markers are intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110772